REMARKS

Upon entry of the amendment, claims 17 and 27-35, and 37-41 will be pending in the application. Claims 26 and 38 are canceled with the present amendment. Support for the amendment to claims 17 and 37 appears in the specification at, e.g., page 16, lines 16-18 and page 18, lines 23-25. New claims 39 and 40 are supported in the specification at, e.g., original claim 17. The claims have additionally been amended so that they no longer recite non-elected matter. No new matter has been added.

The title and abstract have been amended.

Rejection under 35 USC 101

Claims 17, 26, and 30-38 are rejected as drawn to non-statutory subject matter. The rejection is traversed to the extent it is applied to the claims as amended.

Independent claims 17 and 37, from which the remaining claims subject to the rejection depend, have been amended so that are drawn to an isolated antibody. It is believed this amendment overcomes the rejection.

Rejections under 35 USC 112, first paragraph

Claims 17, 30, 32-33, and 35-36 are rejected for overbreadth and for lack of written description. The rejection is traversed to the extent it is applied to the claims as amended.

To the extent the examiner is concerned that the claims encompass an antibody that binds to an epitope other than one that is present in SEQ ID NO:2, claim 17 (from which depends

claims 30, 32-33) has been amended so that it is drawn to an antibody that specifically reacts with an epitope in SEQ ID NO:2.

Applicants submit that the full breadth of the invention now claimed can be practiced without undue experimentation. The specification teaches the amino acid sequences to which the claimed antibody reacts (SEQ ID NO:2), and also provides additional teachings for making and using the claimed antibodies (page 18, line 23 to page 19, line 16):

> Isolated IL-1-R intracellular ligand protein of the invention may also be used to immunize animals to obtain polyclonal and monoclonal antibodies which specifically react with the IL-1-R intracellular ligand protein and which may inhibit IL-1-R intracellular domain binding. Such antibodies may be obtained using either the entire IL-1-R intracellular ligand protein or fragments of IL-1-R intracellular ligand protein as an immunogen. The peptide immunogens additionally may contain a cysteine residue at the carboxyl terminus, and are conjugated to a hapten such as keyhole limpet hemocyanin (KLH). Methods for synthesizing such peptides are known in the art, for example, as in R. P. Merrifield, J. Amer.Chem.Soc. 85, 2149-2154 (1963); J. L. Krstenanisky, et al., FEBS Lett. 211, 10 (1987).
>
> Monoclonal antibodies binding to IL-1-R intracellular ligand protein or to complex carbohydrate moieties characteristic of the IL-1-R intracellular ligand glycoprotein may be useful diagnostic agents for the immunodetection of IL-1-R ligand protein.
>
> Neutralizing monoclonal antibodies binding to IL-1-R intracellular ligand protein or to complex carbohydrates characteristic of IL-1-R intracellular ligand glycoprotein may also be useful therapeutics for both inflammatory conditions and also in the treatment of some forms of cancer where abnormal expression of IL-1-R intracellular ligand protein is involved. These neutralizing monoclonal antibodies are capable of blocking the signaling function of the IL-1-R intracellular ligand protein. By blocking the binding of IL-1-R intracellular ligand protein, certain biological responses to IL-1 are either abolished or markedly reduced. In the case of cancerous cells or leukemic cells, neutralizing monoclonal antibodies against IL-1-R intracellular ligand protein may be useful in detecting and preventing the metastatic spread of the cancerous cells, which may be mediated by the IL-1-R intracellular ligand protein.

One of ordinary skill in the art can readily use this information to make the claimed antibodies using techniques for making antibodies that were well known in the art at the time the present application's priority application was filed.

Applicants also disagree with the Examiner's assertion that the specification does not provide adequate written description for the claimed invention. The test for determining whether a claim fulfills the written description requirement is set forth in Amgen Inc. v. Hoechst Marion Roussel, Inc.[1]

> The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to "recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." Satisfaction of this requirement is measured by the understanding of the ordinarily skilled artisan. ("The description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed'.

[1] 314 F.3d 1313 , 65 USPQ2d 1385, (Fed. Cir. 2003) (internal citations omitted)

An objective standard for determining compliance with written description is whether the disclosure of the application relied upon reasonably conveys to persons of ordinary skill in the art that the Applicant had possession of the claimed subject matter as of the date of the invention.[2,3]

The present rejection can be compared to the written description issue addressed by the Court in Amgen Inc. v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc., 314 F.3d 1313, 85 USPQ2d (BNA) 1385 (Fed. Cir. 2003) In this case, the accused infringer argued that the patentee's claims drawn to "vertebrate cells" in U.S. Patent No. 5,756,349 did not meet the written description provision of 35 U.S.C. §112, first paragraph because the patentee failed to sufficiently describe the use of all vertebrate cells but rather only disclosed CHO (hamster) and COS-1 (monkey) cells in the specification.[4] The patentee argued that there are only "minor differences" in applying the method of the disclosed examples to any vertebrate cells, but that those of ordinary skill in the art could "easily" figure out those differences in methodology. Id. The Court reasoned that the word "vertebrate" readily conveyed distinguishing information concerning identity such that one of ordinary skill in the art could "visualize or recognize the identity of the members of the genus. Id.

[2] *In re Kaslow*, 707 F.2d 1366 (Fed. Cir. 1983)
[3] *In re Gosteli*, 872 F.2d. 1008 (Fed. Cir. 1989)
[4] Amgen Inc. v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc., 314 F.3d 1313 (Fed. Cir. 2003)

Similarly, Applicants submit that the claimed antibody would be readily recognized by one of ordinary skill in the art because the one of ordinary skill in the art would easily recognize an antibody that specifically reacts with an epitope in SEQ ID NO:2, even if that epitope is present on a polypeptide that includes additional amino acid sequences or other structures in addition to those of the amino acid sequence of SEQ ID NO:2. As is disclosed in the specification, it is well known in the art that antibodies to a polypeptide or other antigen of interest can be made by adding an additional structure (such as keyhole limpet hemocyanin) to facilitate production of antibodies.

Applicants submit that, based on the discussion above and the instant specification, one of ordinary skill in the art would reasonably determine that the Applicant had possession of the claimed subject matter as of the date of the invention. Therefore, Applicants respectfully request withdrawal of the present rejection for lack of written description.

Rejection under 35 USC 112, second paragraph

Claims 17, 26, 30-39 are rejected as indefinite for reciting non-elected subject matter in claims 17, 31, 34, and 37. These claims have been amended to delete reference to the non-elected subject matter. Accordingly, this rejection can be withdrawn.

Rejections under 35 102(b)

Claims 17, 30, 32-33, and 35-36 are rejected as anticipated by Hopp et al., US Patent No. 5,011,912. The rejection is traversed to the extent it is applied to the claims as amended.

Claim 17, from which depends claim 20, 23-33 and 35-36, has been amended to require that the antibody bind an epitope within SEQ ID NO:2. Hopp does not describe an antibody that binds to this epitope. Therefore, this rejection can be withdrawn.

A petition for extension of time accompanies this response. The application is believed in condition for allowance, and such action is respectfully requested. The Commissioner is authorized to charge any fees that may be due, or credit any overpayments of same, to Deposit Account No. 50-0311, Ref. No. 22058-568 DIV1A CON.

Respectfully submitted,

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